

## **REMARKS**

### ***Claims Status***

The final Office Action mailed 28 August 2006 rejects all of the claims (Claims 57-64). Upon entry of this amendment, claims 1-64 will be canceled and replaced with new claims 65-71.

### ***New Claims***

The new claims specify, *inter alia*, a dalbavancin composition that is lyophilized and specifies maximum MAG levels pH. Support for the claims is present in the specification. See, e.g., ¶¶ 45, 87-95, and Table 1.

### ***Response to Disclosure Objection***

The disclosure is objected to as not disclosing US patent application numbers in paragraphs 46 and 71. The present amendment is believed to adequately address the objection.

### ***Response to Anticipation Rejection***

Claims 57-62 are rejected under 35 USC § 102(b) or 103(a) over Malabarba et al., Drugs of the Future 24(8):839-846 (1999) ("MALABARBA II"). The rejection states that MALABARBA II discloses a dalbavancin composition that anticipates the claims, and that any differences would appear to be minor and would have been obvious.

Applicants respectfully submit that the rejection should be withdrawn because it is not supported by any explanation of how the applied art is thought to anticipate or render obvious all of the rejected claims. That is, the art is not applied to the claim limitations. Without any written basis for the rejection, there is nothing for Applicants to respond to. Moreover, Applicants submit that the rejection is moot in view of the new claims.

For at least these reasons, reconsideration and withdrawal of the rejection are respectfully requested.

### ***Response to Obviousness Rejection***

Claims 63 and 64 are rejected under 35 USC § 103(a) over MALABARBA II in view of US Patent No. 5750509 to Malabarba et al. ("MALABARBA").

The rejection states that although MALABARBA II does not disclose dalbavancin compositions comprising a stabilizer or being lyophilized, such would have been obvious in view of MALABARBA, which is said to disclose powder compositions with a stabilizing agent.

The rejection further states that the present specification states that dalbavancin often includes MAG and that the MALABARBA II dalbavancin comprises more than 75% B<sub>0</sub>.

The rejection concludes that the MAG levels in the applied art are seen to be inherently the same or very closely related to the claimed levels.

MAG is an undesirable component in dalbavancin compositions, at least because it has a lower activity than B<sub>0</sub>. MAG formation has been found to be pH and temperature dependent. Further, lyophilization has been found to contribute to MAG formation. It has been found that freeze-drying in the presence of an effective stabilizer can reduce MAG formation. Thus, in order to obtain a lyophilized composition containing minimal MAG, it is useful to regulate the pH and to employ an effective stabilizer, as disclosed in the specification.

In view of the above, Applicants respectfully traverse the rejection. Even assuming, according to the rejection, that prior dalbavancin materials contained MAG and >75% B<sub>0</sub>, there is no disclosure or suggestion in the applied art of MAG, a desire to minimize MAG, or a method of minimizing MAG. Naturally, there is also no disclosure or suggestion therein of freeze-drying dalbavancin with a stabilizer or adjusting the pH thereof. Without these measures, a freeze-dried composition would be expected to contain more than the claimed MAG levels. As evidence, US Pat. No. 7119061 (Fig. 1B and Table 4) discloses that lyophilized compositions have initial MAG contents that vary according pH regulation and stabilization or the lack thereof. Thus, even assuming that the applied art discloses a stabilizer with dalbavancin, there is no disclosure or suggestion of how to obtain a lyophilized composition meeting all of the claim limitations. It is also therefore apparent that the claims are therefore not inherent (*i.e.*, anticipated) in the applied art.

Applicants note that the dependent claims more specifically recite features such as pH, B<sub>0</sub>, and the stabilizer.

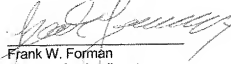
For at least these reasons, reconsideration and withdrawal of the rejection are respectfully requested.

### **Conclusion**

In view of the above, Applicants respectfully submit that the pending claims are allowable in their present form, and that the application is otherwise in condition for allowance. The Examiner is respectfully requested to withdraw the rejection and to provide a Notice of Allowance.

If any issues remain which can be resolved by a telephone conference, or should the Examiner have any questions or comments regarding this matter, the Examiner is respectfully invited to contact the undersigned.

Respectfully submitted,



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